

AUTOMATIC LIQUID PACKAGING, INC.

July 20, 1999

2200 LAKE SHORE DRIVE WOODSTOCK, ILLINOIS 60098-7498 USA
TELEPHONE 815 338 9500 FACSIMILE 815 338 5504
http://www.alp-bfs.com

Food and Drug Administration 5630 Fishers Lane Room 1061 Rockville, MD 20852

RE:

Application for Exemption from 21 CFR 201.66 (OTC Labeling Format)

Artificial Tears

To Whom it may Concern:

Automatic Liquid Packaging Inc., (ALP) is a Contract Manufacturer of OTC Ophthalmic Eye Care Products, located in Woodstock, Illinois. We contact manufacture for retail companies such as Rite Aid, Walgreen's, Sentry, etc.

For approximately 8 – 10 years we have been manufacturing and distributing a line of eye drops manufactured by our internal Personal Care division of ALP in 0.5 and 1.0 fluid Ounce Sizes. This line of products is in compliance as outlined in **21 CFR 349.** The line consists of the following:

PRODUCT NAME

ACTIVE INGREDIENT

Artificial Tears

Polyvinyl Alcohol (a demulcent) Povidone (a demulcent)

All the active ingredients conform to USP and are in compliance to the percents of Active Ingredients allowed in 21 CFR 349.

Automatic Liquid Packaging, Inc., is requesting an Exemption from the labeling requirements as described in Federal Register published March 17, 1999 entitled "Over-The-Counter Human Drugs; Labeling Requirements" for our 0.5 and 1.0 Fluid Ounce size container box. The reason for this is that when all the Agency required labeling statements are included on the back panel in the new format and Helvetica type size, there is no room for the additional FDA labeling requirements.

Please refer to the attached copies of the carton and immediate container labeling that is included in this Application. Note the Helvetica type size and arrangement of the required statements on the Principle Display Panel.

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APP5

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In addition, note the placement of statements such as Storage requirements, Manufactured by, Bar coding, Tamper evident, and Eye Drop Container opening instructions Statements such as this also must appear on the outside package.

As such, Automatic Liquid packaging requests an exemption from the Helvetica Labeling letter size requirements, as described in **21 CFR 201.66** (OTC Labeling Format) for the above mentioned Ophthalmic drops for our 0.5 and 1.0 fluid ounce size.

As mentioned previously in the Request for Exemption, ALP is a Contract Manufacturer of OTC Ophthalmic Eye Drops for many Retail Distributors. If the Agency will allow the requested modifications to the Principle Display Panel as attached, we also request approval for the retail distributors we manufacture the same ophthalmic product line. These distributors are detailed in the list attached to this letter. As you could imagine, from time to time, ALP will aquire a new distributor. If the Agency allows the modified text for our in-house "Your Choice" line, as well as our current list of distributors, we respectfully request that any new distributors we add be allowed these same modifications. ALP commits that the information included on the Principle Display Panel and side panels would be identical as shown in the Attachments for all present and future distributors we manufacture this eye drop line.

Please contact me at (815) 338-9500 with any questions, or if you require any additional information.

Sincerely,

AUTOMATIC LIQUID PACKAGING, INC.

John Brda

Regulatory Affairs Manager

e Al Rothchild

.5 Oz. Artificial Tear Eye Drops

Logo

Artificial Tears

· Lubricant Eye Drops

.5 fl. oz. (15 mL)

RIDICATIONS: for the temporary relief of burning and inflation due to dryness of the eye DIRECTIONS. Instill 1 or 2 drops in the affected eye(s) as needed FOR USE BUT REFERSIONS.

WARRINGS: Before using with children under 6 years of age, consult your physician Resp this and all drugs out of the reach of children in case of accidental legislation, seek professional assistance or contact a Potono Conflox Cerefor immediately Note warrings on both active highest-wise. Polyviery Accident, 1.4% and Povidone 0.5% and Active highest-wise. Polyviery Accident, 1.4% and Povidone 0.5% inactive highest-wise. Polyviery Accident, 1.4% and Povidone 0.5% macritical begreaters, benzilkenium choride. DITA, putified water, sedium children, column prosphate morobasis; and disastic experiences of the properties of the provision of the properties. The provision of t

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1 Oz. Artificial Tears Eye Drops

Logo

Artificial Tears

· Lubrit int Eye Drops

1 fl. oz. (30 mL)

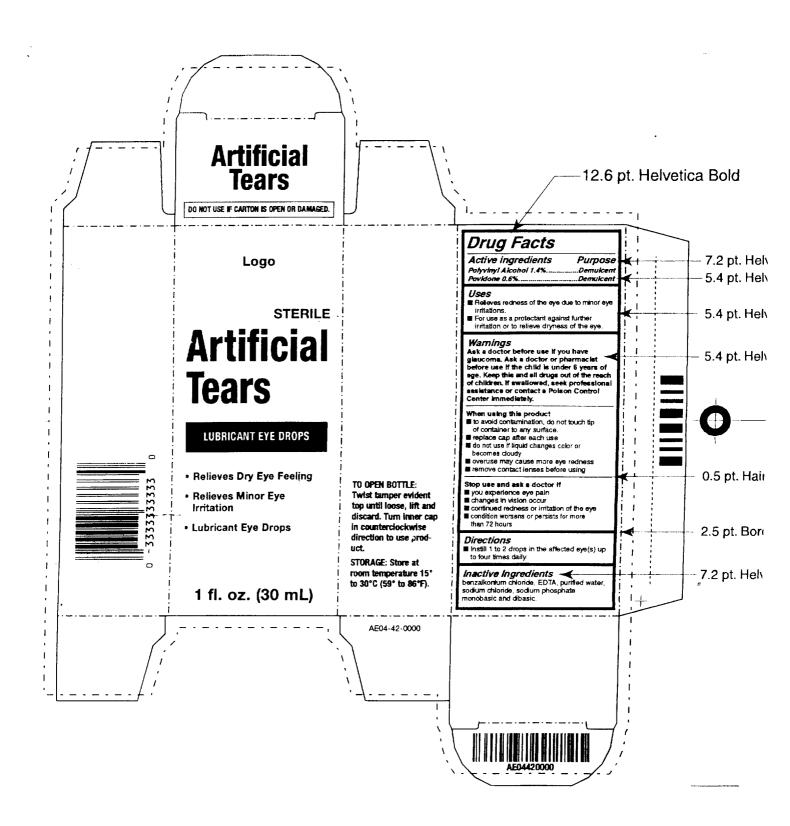
MOCATIONS: For the temporary relief of discomfort from minor eye initiations. Relieves reduces of the eye due to minor eye initiations. DIRECTIONS: instill 1 to 2 drops in the affected eye(s) as needed. For USE IN THE EYES DALK.

WARRINGS: Before using with riddern under 6 years of age, consult your physician. Keep this and all drups but of the reach of children in case of — certail injection, seek professional assistance or contact a Poison Control Center immediately. Mole warnings on box.

Active largeralents: Ponyshyl Acohol. 1.4% and Pevidone 0.6% Inactive largeralents: Ponyshyl Acohol. 1.4% and Pevidone 0.6% Inactive largeralents: Ponyshyl Acohol. 1.4% and Pevidone 0.6% Inactive largeralents: Tonyshyl Acohol. 1.4% and Pevidone 0.6% Inactive largeralents: Ponyshyl Acohol. 1.4% and Pevidone 1.6% Inactive largeralents: Ponyshyl Acohol.

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.5 Oz. Artificial Tear Eye Drops

Logo Sterile

Artificial Tears

· Lubricant Eye Drops

.5 fl. oz. (15 mL)

INDICATIONS: for the temporary relief of burning and initiation due to dryness of the eye.

DIRECTIONS: Insult 1 or 2 drops in the affected eye(s) as needed FOR USE BY THE EYES ORLY.

WARNINGS: Refere using with children under 6 years of age, consult your physician. Resp this and at days and of the resh of children in case of accidental ingestion, seek professional assistance or contact a Polson Control Cerebre Immediately Mike warrangs on the Orchiders of Children in Case of accidental ingestion, seek professional assistance or contact a Polson Control Cerebre Immediately Mike warrangs on the Active Impediately Experience of the Active Impediately Experience of the Active Impediately Experience (Assistance of Control Control Cerebre Immediately Mike warrangs on the purified water, sodium chordes, sodium phosphate monobasic and dibasic.

REED CONTRIBET SPITITE COURSE.

TAMPER EXPENDENT E TAMPER EXPENT CAP IS REMOVED, DO NOT USE Distributed by or Manufactured by

1 Oz. Artificial Tears Eye Drops

Logo

Artificial Tears

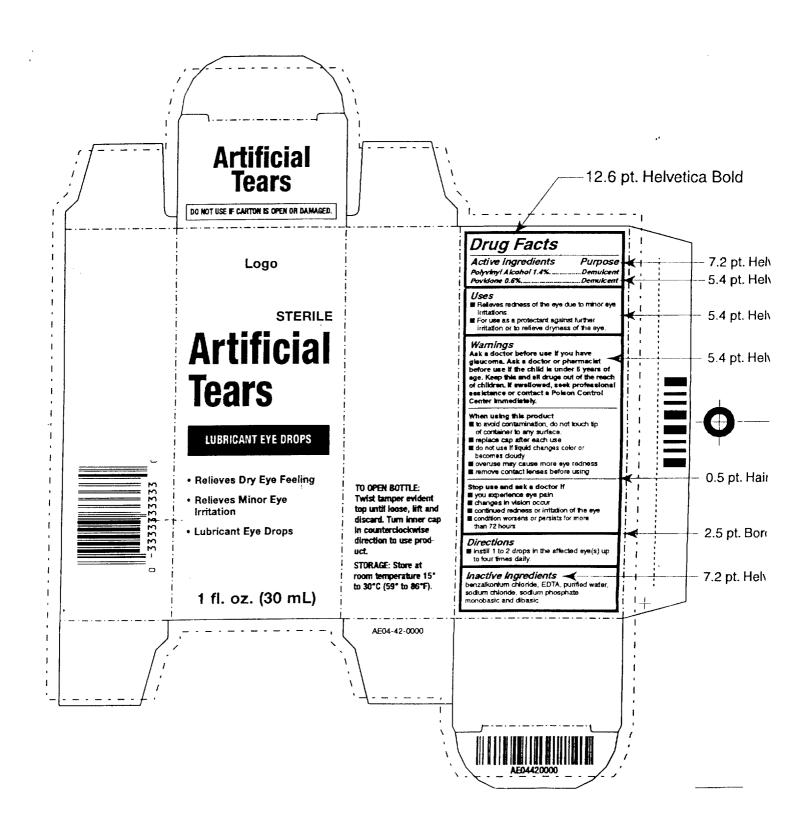
· Lubricant Eye Drops

1 fl. oz. (30 mL)

INDICATIONS: for the temporary relief of discomfort from minor eye irritations. Relieves redness of the eye due to minor eye irritations. DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) as needed. FOR USE IN THE EYES ONLY.
WARNINGS: Before using with children under 6 years of age, consult your physicien. Reep this and all drugs out of the reach of children, in case of accidental ingestion, seek professional assistance or contact a Proson Control Center immediately, Note warmings on box.
Active Ingradients: Prophylyl Alcohol. 1 As and Pavidena 0.5% Inactive Ingradients: Denzakonium childrice, EDTA, purified water, sodium childrice, docum phosphate amonobasks and disastic. maketive agreement extraction of the control of the

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.5 Oz. Artificial Tear Eye Drops

Logo

Artificial

· Lubricant Eye Drops

.5 fl. oz. (15 mL)

Tears

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WARNINGS: Before using with children under 6 years of age, consult your physician Resp this and a facus so at of the respect of children in case of accidental ingestion, seek professional assistance or contact a poton Corona, relief Immediately, lower writings on both Active Impediately, New avarings on both Active Impediately, New avarings on both Active Impediately, the warrings on the Active Impediately, and Povisione 0.5% heactive Impediately New avarings on the Active Impediately and Povisione 0.5% active Impediately in Active Impediately, purified water, sodium choide, sodium phosphate monobasic and dibasic.

REEP CONTRINET INTIC CLOSED.

TAMPICE RUMENT: FLAMITIC EVECNT CAP IS REMOVED, DO MOT USE.

Distributed by or Manufactured by

1 Oz. Artificial Tears Eye Drops

Logo

Artificial Tears

· Lubric •nt Eye Dreps

1 fl. oz. (30 mL)

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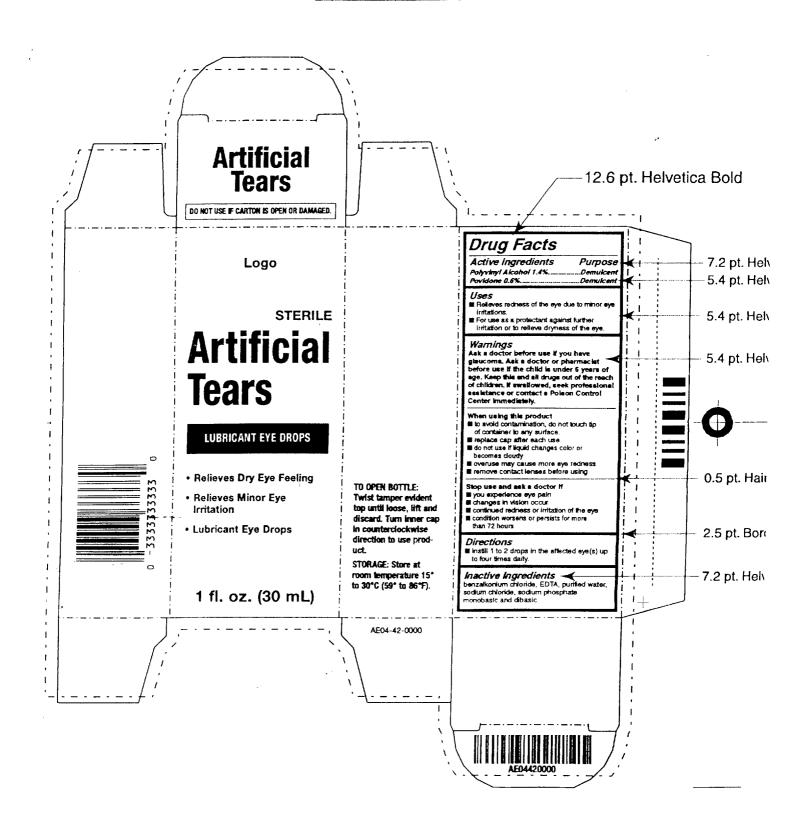
WARNINGS: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of — 3 mail ingestion, seek professional assistance or contact a Poison Control Center immediately. Note warnings on box.

Active ingradients: Polyving Acentu. 1.4% and Povidions 0.6% inactive ingradients: England microbiosis and dibasic KEEP CONTAINER TRUTTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP (S REMOVED, OO NOT USE DISS. Schied by or Manufactured by:

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EYEDROPS .5 OZ. AND 1 OZ.

FIRST AID/SAFETY MARKET

.5 oz. Tetra

MIAMI MARKET-EXPORT

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Relief Eyedrops
- .5 oz. Artificial Tears

AARP Retired Persons Pharmacy

- 1 oz. F-455 PVA Lubricant Eyedrops
- 1 oz. F-707 PVA Povidone Eyedrops
- 1 oz. R-450 Eyedrops
- 1 oz. Extra Eyedrops
- 1 oz. Relief Eyedrops

ALBERTSONS

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops

ALPINE DISTRIBUTORS

.5 oz. Tetra Eyedrops

AMERICAN DRUG

- .5 oz. Extra Eyedrops
- .5 oz--Relief Eyedrops

AMES

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Relief Eyedrops
- .5 oz. Artificial Tears

BRUNOS

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Relief Eyedrops

CERTIFIED GROCERS

. 5 oz. Tetra Eyedrops

DEMOULAS

- .5 oz. Tetra Eyedrops
- .5 Extra Eyedrops

DUANE READE

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Relief Eyedrops
- .5 oz. Artificial Tears

FEDERATED FOODS

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Relief Eyedrops
- .5 oz. Artificial Tears

GENOVESE

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Relief Eyedrops
- .5 oz. Artificial Tears

GRANDALL

. 5 oz. Tetra Eyedrops

GRANDPAS

.5 ozt Tetra Eyedrops

GRAND UNION

.5 oz. Tetra Eyedrops

HARMON DISCOUNT

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Relief Eyedrops
- .5 oz. Artificial Tears

HARRIS TEETER

- 1 oz. Tetra Eyedrops
- 1 oz. Relief Eyedrops

KROGER/PEYTON

- 1 oz. Tetra Eyedrops
- 1 oz. Extra Eyedrops
- 1 oz. Relief Eyedrops

LONGS

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Relief Eyedrops
- .5 oz. Artificial Tears
- 1 oz. Tetra Eyedrops
- 1 oz. Extra Eyedrops
- 1 oz. Relief Eyedrops

MARSH

.5 oz. Tetra Eyedrops

MCCLANE/CVP

.5 oz. Tetra Eyedrops

NASH FINCH

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Artificial Tears

PAHTMARK

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Relief Eyedrops
- .5 oz. Artificial Tears

PUBLIX

- .5 oz. Tetra Eyedrops
- .5 oz. Relief Eyedrops
- .5 oz. Artificial Tears

REPUBLIC DRUGS

.5 oz. Tetra Eyedrops

RITE AID

- 1 oz. Tetra Eyedrops
- 1 oz. Extra Eyedrops
- 1 oz. Relief Eyedrops

SAFEWAY/VONS

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Tetra Eyedrops

SHOPKO

- .5 oz. Tetra Eyedrops
- .5 oz. Artificial Tears

SUPERMARKET SERVICES

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Relief Eyedrops
- .5 oz. Artificial Tears

VALUE STAR

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Relief Eyedrops
- .5 oz. Artificial Tears

WALGREENS

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Relief Eyedrops
- .5 oz. Artificial Tears

WINN DIXIE

- .5 oz. Tetra Eyedrops
- .5 oz. Extra Eyedrops
- .5 oz. Relief Eyedrops
- .5 oz. Artificial Tears